

We Claim:

1. A process for preparing a chewable or disintegrative tablet, comprising forming a tablet having a friability of less than about 2% from a mixture comprising a pharmaceutically active ingredient, an excipient in the form of a hydrate, and a water-swelling excipient, and then applying sufficient energy to the tablet for a sufficient time to decrease the hardness of the tablet by at least about 20%.
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2. The process of claim 1, wherein energy is provided to the tablet in the form of heat.
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3. The process of claim 1, wherein the tablet is formed by direct compression.
4. The process of claim 1 wherein the tablet has a final hardness of less than about 15 kp/cm².
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5. The process of claim 1, wherein the friability is less than about 1% and the tablet has a final hardness in the range of about 1-8 kp/cm².
6. The process of claim 1, wherein prior to application of energy to the tablet, the tablet is packaged.
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7. The process of claim 1, wherein the active ingredient is selected from the group consisting of acetaminophen, ibuprofen, pseudoephedrine, dextromethorphan, diphenhydramine, chlorpheniramine, calcium carbonate, magnesium hydroxide, magnesium carbonate, magnesium oxide, aluminum hydroxide, mixtures thereof, and pharmaceutically acceptable salts thereof.
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8. The process of claim 1, wherein the excipient in the form of a hydrate is selected from the group consisting of dextrose monohydrate, maltodextrin, lactose monohydrate, dextrin, citric acid monohydrate, dibasic calcium phosphate dihydrate, dibasic
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sodium phosphate dihydrate, dibasic sodium phosphate heptahydrate, dibasic sodium phosphate dodecahydrate, monobasic sodium phosphate monohydrate, and monobasic sodium phosphate dihydrate.

5 9. The process of claim 1, wherein the water-swella-
ble excipient is selected from the group consisting of sodium starch glycolate, crospovidone, croscarmellose, microcrystalline cellulose, starches, and alginic acid.

10 10. The process of claim 1, wherein the tablet contains about 5 to about 90 % by weight of excipient in the form of a hydrate based on the total weight of the tablet.

11. The process of claim 1, wherein the tablet contains about 0.1 to about 5 % by weight of water-swella-
ble excipient based on the total weight of the tablet.

15 12. The process of claim 1 wherein the excipient in the form of a hydrate functions as a direct compression filler.

13. A tablet produced by the process of claim 1.

20 14. A tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing, comprising a) a pharmaceutically active ingredient, b) an excipient at least partially in the form of a hydrate, and c) a water-swella-
ble excipient that is at least partially hydrated.

25 15. The tablet of claim 14, wherein the active ingredient is selected from the group consisting of acetaminophen, ibuprofen, pseudoephedrine, dextromethorphan, diphenhydramine, chlorpheniramine, calcium carbonate, magnesium hydroxide, magnesium carbonate, magnesium oxide, aluminum hydroxide, mixtures thereof, and pharmaceutically acceptable salts thereof.

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16. The tablet of claim 14, wherein the excipient in the form of a hydrate is selected from the group consisting of dextrose monohydrate, maltodextrin, lactose monohydrate, dextrin, citric acid monohydrate, dibasic calcium phosphate dihydrate, dibasic sodium phosphate dihydrate, dibasic sodium phosphate heptahydrate, dibasic sodium phosphate dodecahydrate, monobasic sodium phosphate monohydrate, and monobasic sodium phosphate dihydrate.

17. The tablet of claim 14, wherein the water-swellable excipient is selected from the group consisting of sodium starch glycolate, crospovidone, croscarmellose, microcrystalline cellulose, starches, and alginic acid.

18. The tablet of claim 14 having a hardness of less than about 15 kp/cm².

19. A tablet comprising: a) a pharmaceutically active ingredient, b) dextrose monohydrate, and c) crospovidone.

20. The tablet of claim 19 having a hardness of less than about 15 kp/cm².

21. The tablet of claim 14 which is substantially free of water-soluble, non-saccharide polymeric binders.

22. The tablet of claim 14 wherein the excipient that is at least partially hydrated has an average particle diameter of about 100 to about 400 microns.

23. The tablet of claim 14 wherein the weight ratio of the excipient in the form of a hydrate to the water-swellable excipient is from about 1:1 to about 150:1.